FEB 2 6 2014

Traditional 510(k) Summary

The following 510(k) summary has been prepared pursuant to requirements specified in 21CFR 807.92.

807.92(a)(1)

Submitter Information

EB Neuro, S.p.A.
Via Pietro Fanfani 97/a
Florence, Italy 50127

Contact Person: Allison Scott
317.228.8719
Allison.Scott@Navigant.com

Date: January 17, 2014

807.92(a)(2)

Devices

Common Name: Physiological Signal Amplifier

Trade Name: Nemus 2

Classification Name(s): Physiological Signal Amplifier

Classification Number: 21 CFR 882.1835 Physiological signal amplifier, Product Code GWL
21 CFR 882.1870 Evoked response electrical stimulator, Product Code GWF
21 CFR 882.1890 Evoked response photic stimulator, Product Code GWE
21 CFR 882.1900 Evoked response auditory stimulator, Product Code GWJ

Regulatory Class: Class II

807.92(a)(3)

Predicate Device(s)

Device	Owner	510(k)
Nemus 1	EB Neuro	K073415
BE Plus LTM	EB Neuro	K121996

807.92(a)(4)

Device Description

The Nemus 2 System is made up of the Nemus 2 Amplifier/Stimulator, an AC/DC converter to power the amplifier, a "junction box" to connect the system to the Host PC, and (optionally) by a dedicate keyboard and a Flash LED stimulator.

The Nemus 2 System is intended to acquire bioelectric signals produced by the patient's central and peripheral nervous system and muscles. The acquired signals are transmitted to a PC during recording of neurophysiology examinations. The device may use electrical stimulus, sound stimulus, or visual stimulus for use in evoked response analysis.

The Nemus 2 System is an amplifier/stimulator device especially developed to amplify biological signals. The amplifier captures the biological signal from the human body through specialized sensors or electrodes, amplifies the very low electrical signal, and filters it to accomplish an antialiasing in order to make an optimal ANALOG to DIGITAL conversion. The data, once converted in numerical form, are "passed" to a host computer, which at this point is free to elaborate the data following the logic of the application software running on the host. The Nemus 2 System is not involved in the data management performed by the host.

807.92(a)(5)

Intended Use

The Nemus 2 System is intended to acquire the bioelectric signals produced by the patient's central and peripheral nervous system and muscles. The acquired signals are transmitted to a PC during recording of neurophysiology examinations. The Nemus 2 System consists of a physiological signal amplifier, an evoked response auditory stimulator, an evoked response electrical stimulator, and an evoked response photic stimulator. The user needs to assure compatibility of the Nemus 2 System to the other components of the user's own system.

807.92(a)(6)

Technological Characteristics

The Nemus 2 is very similar to the Nemus 1 both from the hardware and the software point of view. Nemus 2 may be considered an "enhanced" version of Nemus 1. Practically the Nemus 2 is a Nemus 1 with an added internal board deputed to the Acquisition of the 20 EEG/EP channels. The case is practically identical with the obvious exception of the upper panel in which, in the Nemus 2 have been allocated the input sockets for the added channels.

In particular in relation to the internal stimulators:

- The audio stimulator is absolutely identical
- The electric stimulator of the Nemus 2 is the same of the Nemus 1, but with the difference that in the Nemus 2 the electric pulse may be delivered to 5 different output sockets. Under control of the firmware the stimulus may be delivered on one of this 5 output, but only one may be active at the same time, so also the Nemus 2 simulator has "only" one output. Apart from this aspect the two stimulators are identical.

The two devices use the same AC/DC mains adapter.

Parts of the system external the "Base unit" (the amplifier), i.e. the connection box, the link cable, the stimulation probe, the optional dedicated myographic keyboard, are the same for both devices.

The firmware is substantially the same with the only obvious exception of the managing of the added 20 EEG/EP channels. Apart from this, the host communication protocol is the same for both devices.

Differently from the Nemus 1, The Nemus 2 can handle, as an option, the EBNeuro Flash LED stimulator, useful during EEG or Visual Evoked Potential exams.

The Nemus 2 20 EEG/EP channels use the same technology of the 64 channels of the BE Plus LTM.

The part of Nemus 2 host communication protocol related to the transmission of the EEG data is substantially the same to the BE Plus LTM due to the fact that the processing architecture is very similar.

The Nemus 2 and BE Plus LTM devices can handle the same (optional) EBNeuro Flash LED stimulator.

The Nemus 2 and BE Plus LTM devices use the same AC/DC mains adapter. However the BE Plus LTM may be powered also from internal batteries.

An obvious difference is that the BE Plus LTM is not capable to handle EMG channels due to absence of internal stimulator and due to the technical characteristic of its acquisition channels (band, sampling rate, etc)

Substantial Equivalence Comparison Table

Product Characteristic	Nemus2 OEM System (submission device)	Nemus1 System (Predicate Device)	BE Plus LTM (Predicate Device)
Regulatory			
Manufacturer	EBNeuro S.p.A.	EBNeuro S.p.A.	EBNeuro S.p.A.
510(k) number	TBA	K073415	K121996
Device class	Class II	Class II	Class II
Product code	GWL, GWF,GWJ, GWE	IKN, GWF,GWJ,JXE	GWL
Device type	Physiological signal Amplifier, Electrical stimulator, Audio, photic stimulator	Electromyograph	Physiological signal Amplifier,
Regulation Number	882.1835	890.1375	882.1835

Product Characteristic	Nemus2 Amplifier (submission device)	Nemus1 System (Predicate Device)	BE Plus LTM (Predicate Device)
Labeling			
Intended use	The Nemus 2 System is intended to acquire the bioelectric signals produced by the patient's central and peripheral nervous system and muscles. The acquired signals are transmitted to a PC during recording of neurophysiology examinations. The Nemus 2 System consists of a physiological signal amplifier, an evoked response auditory stimulator, an evoked response electrical stimulator, and an evoked response photic stimulator. The user needs to assure compatibility of the Nemus 2 System to the other components of the user's own system.	The Nemus1 system is intended to monitor, record and display the bioelectric signals produced by muscles, to stimulate peripheral nerves and to monitor record and display the electrical activity produced by nerves to aid the clinician in the diagnosis and prognosis of neuromuscular disease (EMG). The device may use electrical stimulus or sound stimulus for use in evoked response measurements (EP).	Acquisition of EEG, polygraphy and polysomnography signals and transmission of these to a PC during recording of neurophysiology examinations
Warnings	Items related to off-label use	same	same
Contraindication	Items related to design and indicated use limitations, such as not for use in the presence of flammable anesthetics or in conjunction with defibrillation equipment	same	same
Target population	Pediatric through adult	same	same
Environment of use	Hospitals, laboratory, institutions, or other test environments The device may be placed in Intensive Care Unit or	Hospitals, institutions, or other test environments.	Hospitals, institutions, or other test environments

Product Characteristic	Nemus2 Amplifier (submission device)	Nemus1 System (Predicate Device)	BE Plus LTM (Predicate Device)
	Operating Room for continuous recording.		
Prescription status	Available only on the order of a physician	same	same
User Service	No user service allowed	same	same
Design - General			
The device acquire bioelectric signals produced by muscles and nerves (EMG)	YES	YES	NO
Device acquire the electrical activity of the brain (EEG/EP)	YES	NO	YES
Patient inputs	2 EMG channels 20 EEG/EP channels	2 EMG channels	64 EEG channels
Signal acquisition	Analog-to-digital conversion at variable sampling rate	same	same
Safety Standards	IEC 60601-1 IEC 60601-1-1 IEC 60601-1-2 IEC 60601-1-4 IEC 60601-2-26 IEC 60601-2-40	IEC 60601-1 IEC 60601-1-1 IEC 60601-1-2 IEC 60601-1-4 IEC 60601-2-40	IEC 60601-1 IEC 60601-1-1 IEC 60601-1-2 IEC 60601-1-4 IEC 60601-1-6 IEC 60601-2-26
Patient circuitry isolation	Optic EMG channels inputs, electrical stimulator outputs: BF Type Acoustic stimulator headphones: BF Type External serial ports and I/O: B Type EP\EEG channels inputs: CF Type	Optic EMG channels inputs, electrical stimulator outputs: BF Type Acoustic stimulator headphones: BF Type External serial ports and I/O: B Type	Optic Patient isolation BF type Auxiliary I/O components ports: B type

Product Characteristic	Nemus2 Amplifier (submission device)	Nemus1 System (Predicate Device)	BE Plus LTM (Predicate Device)
System Components	Nemus 2 Base Unit (Amplifier) AC/DC Adapter Dedicated Keyboard (optional) LED Flash Stimulator (optional)	Nemus 1 Base Unit (Amplifier) AC/DC Adapter Dedicated Keyboard (optional)	Amplifier Unit AC/DC Adapter Removable 64/32 ch. Patient Box Rechargeable battery pack Battery pack charger Mixed power/Ethernet link cabling Expansion cable LED Flash Stimulator (optional
Amplifier-Computer interface	LAN Ethernet IEEE 802.3	same	"wired LAN " ETHERNET/IEEE 802.3 or "wireless LAN " WLAN/IEEE 802.11
Amplifier Power Supply	External IEC 60601-1 mains adapter	same	External IEC 60601-1 mains adapter or Internal battery pack
Size (H/W/D) mm	Nemus 2 Amplifier 170 (L) x 125 (W) x 35 (H) (mm)	Nemus 1 Amplifier 170 (L) x 125 (W) x 35 (H) (mm	188 (L) x 148 (W) x 40 (H) (mm)
Weight	Nemus 2 Amplifier 0.6 Kg	Nemus 1 Amplifier 0.45 Kg	0.5 Kg
Case material	Nemus 2 Amplifier Policarbonate Macrolon 6557 UL VO	Nemus 1 Amplifier Policarbonate Macrolon 6557 UL VO	ABS Resin – (AF312B).

Product Characteristic	Nemus2 System (submission device)	Nemus1 System (Predicate Device)	BE Plus LTM (Predicate Device)
Design - Acquisition			
Number of channels	2 EMG 20 EEG/EP	2 EMG	64 EEG
CMRR	>100 dB	>100 dB	>98 dB
IMRR	>100 dB	>100 dB	>98 dB
Input impedance	EMG Channels : same as Nemus 1 EEG/EP channels: same as BE Plus LTM	EMG Channels : >100 MΩ	EEG Channels: Comm. Mode : 3.3 MΩ Differential : 6.6 MΩ
Noise	EMG Channels : < 0.3 μVrms (0.1 – 100 Hz) EEG/EP channels: <20 nV/√Hz (10-10KHz)	EMG Channels : < 0.3 μVrms (0.1 – 100 Hz)	EEG Channels: <0.3μVrms (@256 Hz sampling rate)
A/D conversion	24 bit (2 EMG bipolar channels) 16bit (20 EEG/EP unipolar channels)	24 bit (2 EMG bipolar channel)	16 bit (64 EEG unipolar channels)
Sampling rate	16384 Hz (EEG/EP ch) 32768 Hz (EMG ch) Oversampling = Fs x 128	32768 Hz (EMG ch) *Oversampling* = Fs x 128	8192 Hz/Channel
Antialiasing Low pass filter	EMG ch. : 20 KHz EEG/EP ch, _ 2 KHz	EMG ch. : 20 KHz	2KHz 3rd order filter
High-pass Filter	1.6s (0.1 Hz) or 16ms(10Hz)(EMG channels) 1.6/160 ms (0.1/1 Hz) (EEG/EP channels	1.6s (0.1 Hz) or 16ms(10Hz)(EMG channels	selectable 0.1/10 Hz 1st order filter
Trigger mode	Free, Auto, Internal, External	same	na
Ohmmeter	0-100 kOhm (auto full scale)	same	same

Product Characteristic	Nemus System (submission device)	Nemus1 System (Predicate Device)	BE Plus LTM (Predicate Device)
Design - Stimulators			
Electric Stimulator	Type: *constant current* N. output : 1 Max output : *100 mA* Pulse width: *0.05 – 1ms* Mode: *single, train*	Type: *constant current* N. output : 1 Max output : *100 mA* Pulse width: *0.05 – 1ms* Mode: *single, train*	None
Audio Stimulator	Output mode: *click, tone* Sound pressure: *0-132 dB SPL* Phase: *condens., raref., alternate* Signal frequency: *125-8000 Hz* Plateau time: *1-200 ms* Rise/fall time: *1-100 ms* Mask level: *-40 - +10 dB (relative)* Click width: *1-100 µs* Stimulus presen. *Left, right, binaural* Output: Headset *TDH 39*	Same audio stimulator	None
Visual Stimulator	Led Flash Stimulator (optional – same device as BE Plus LTM)	None	Led Flash Stimulator (optional)

807.92(b)(1)

Summary of Non-Clinical Tests

The devices have been evaluated for electrical, electromagnetic, and mechanical safety, and have been found to conform to the following medical device safety standards.

- IEC 60601-1
- IEC 60601-1-1
- IEC 60601-1-2
- IEC 60601-1-4
- IEC 60601-2-26
- IEC 60601-2-40

Verification testing was conducted to demonstrate that the Nemus 2 met technical specifications including saturation, polarization, offset & gain, noise, CMRR, IMRR, and input impedance. The testing successfully verified that the Nemus 2 meets the technical specifications.

807.92(b)(2)

Summary of Clinical Tests

No clinical tests were performed.

807.92(b)(3)

Conclusion

The Nemus 2 is substantially equivalent to the legally marketed devices and conforms to applicable medical device safety and performance standards.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Center – WO66-G609
Silver Spring, MD 20993-0002

February 26, 2014

EB Neuro, S.p.A.
c/o Ms. Allison Scott, RAC
Navigant Consulting, Inc.
9001 Wesleyan Road, Suite 200
Indianapolis, IN 46268

Re: K133517
Trade/Device Name: Nemus 2 System
Regulation Number: 21 CFR 882.1835
Regulation Name: Physiological Signal Amplifier
Regulatory Class: Class II
Product Code: GWL
Additional procodes: GWF, GWE, GWJ
Dated: January 20, 2014
Received: January 22, 2014

Dear Ms. Scott:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set

forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Joyce M. Whang -S

for Carlos L. Peña, Ph.D., M.S.
Director
Division of Neurological
And Physical Medicine Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

Indications for Use

Form Approved: OMB No. 0910-0120
Expiration Date: December 31, 2013
See PRA Statement on last page.

510(k) Number *(if known)*
K133517

Device Name
Nemus 2 System

Indications for Use *(Describe)*

The Nemus 2 System is intended to acquire the bioelectric signals produced by the patient's central and peripheral nervous system and muscles. The acquired signals are transmitted to a PC during recording of neurophysiology examinations. The Nemus 2 System consists of a physiological signal amplifier, an evoked response auditory stimulator, an evoked response electrical stimulator, and an evoked response photic stimulator. The user needs to assure compatibility of the Nemus 2 System to the other components of the user's own system.

Type of Use *(Select one or both, as applicable)*

☒ Prescription Use (Part 21 CFR 801 Subpart D) ☐ Over-The-Counter Use (21 CFR 801 Subpart C)

PLEASE DO NOT WRITE BELOW THIS LINE – CONTINUE ON A SEPARATE PAGE IF NEEDED.

FOR FDA USE ONLY

Concurrence of Center for Devices and Radiological Health (CDRH) *(Signature)*

Joyce M. Whang -S